[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request:

Cognitive Testing of Instrumentation and Materials for the Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on May 23, 2012, page 30540 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION**:** Title*:* Cognitive Testing of Instrumentation and Materials for Population Assessment of Tobacco and Health (PATH) Study. Type of Information Collection Request: New. Need and Use of Information Collection:

The PATH study will establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions implemented as part of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) by the Food

and Drug Administration (FDA). NIDA is requesting generic approval from OMB for cognitive testing of the PATH study's instrumentation, supporting materials, consent forms, and methods of administration (e.g., computer assisted personal interviews [CAPI], audio computer assisted self-interviews [ACASI], web-based interviews). Cognitive testing of these materials and methods will help to ensure that their design and content are valid and meet the PATH study's objectives. Additionally, results from cognitive testing will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of the information collection to help minimize its estimated cost and public burden.

Frequency of Response: Annual [As needed on an on-going and concurrent basis].

Affected Public: Individuals and Households. Type of Respondents*:* Youth (ages 12-17) and Adults (ages 18+). The annual reporting burden for the screening of respondents for the PATH study cognitive testing is presented in Table 1, and the annual reporting burden for the PATH study cognitive testing is presented in Table 2. The annualized cost to respondents for participating in screening for PATH study cognitive testing is estimated at: $6,632; and the annualized cost to respondents for participating in PATH study cognitive testing is estimated at: $20,346. There are no capital, operating or maintenance costs.

Table 1. Estimated Annual Reporting Burden for Screening of PATH Study Cognitive Testing Respondents

Screening for Respondents	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
Screener	Youth	1000	1	$^{10}/_{60}$	167
	Adult	2000	1	$^{10}/_{60}$	333
TOTAL		3000			500

Table 2. Estimated Annual Reporting Burden Summary - Cognitive Testing of Instrumentation and Forms for the PATH Study

Instrument / Form to be Tested	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
Forms to support data collection*	Adult	200	1	1 $^{30}/_{60}$	300
Assent forms for participation in PATH study	Youth	200	1	1 $^{30}/_{60}$	300
Consent forms for participation in PATH study	Adult	200	1	1 $^{30}/_{60}$	300
PATH study questionnaires	Youth	100	1	1 $^{30}/_{60}$	150
	Adult	300	1	1 $^{30}/_{60}$	450
TOTAL		1000			1500

* For example, letters, mailing envelopes, PATH study brochures, instructions for collection of biospecimens.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget,

Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; 301-443-8755; email PATHprojectofficer@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: August 30, 2012

Glenda P. Conroy

Executive Officer (OM Director), NIDA

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